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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/559,759   | 12/05/2005  | Sadao Omata          | MOR-261-A           | 3839             |
| 48980 77590 977242908<br>YOUNG & BASILE, P.C.<br>3001 WEST BIG BEAVER ROAD |             |                      | EXAMINER            |                  |
|  |             |                      | TANNER, JOCELIN C   |                  |
| SUITE 624<br>TROY, MI 48   | 084         |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3731                |                  |
|  |             |                      |                     |                  |
|  |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|  |             |                      | 07/24/2008          | EL ECTRONIC      |

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Application No. Applicant(s) 10/559,759 OMATA ET AL. Office Action Summary Examiner Art Unit JOCELIN C. TANNER 3731 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 30 April 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-10 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-10 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 05 December 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/S5/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

Application/Control Number: 10/559,759 Page 2

Art Unit: 3731

#### DETAILED ACTION

# Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite part of the human body in combination with the device, e.g. a duct. It has been held that a claim directed to or including within its scope, a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of limited, but exclusive property right in a human being is prohibited by the constitution.

In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970). For examination purposes, all claims will be considered as if such limitations involving the combination with a human were not present.

### Claim Rejections - 35 USC § 102

 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filted in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

 Claims 1 and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Noriega et al. (US Patent No. 6.824.550). Application/Control Number: 10/559,759 Page 3

Art Unit: 3731

3. Regarding claim 1, Noriega et al. discloses an elongate member or "flexible insertion tube" (14) into which a flexible drive shaft or "wire" (22) is inserted and a drive motor or "rotating device" (26) that imparts rotational, advancement and retraction movement to the wire thereby allowing the wire to reside within or outside the insertion tube and causes the tip of the insertion tube to vibrate when contacted by the rotating wire (column 7, lines 1-3 and 23-26, column 9, lines 27-32, column 8, lines 36-39, column 10. lines 51-52. Fig. 1A).

- Regarding claim 4, Noriega et al. discloses a wire (22) having a curved tip wherein the distal tip can be shaped or deflected from the longitudinal axis (column 8, lines 45-46, Figs. 4, 5A-5C, 8J, and 8K).
- 5. Regarding claims 5 and 7, Noriega et al. discloses an access system or "intraductal foreign body removal instrument" (10) that is adapted for introduction to a target vessel through a selected catheter (column 2, lines 55-57, column 3, lines 9-13).
- 6. Regarding claim 6, 8 and 9, Noriega et al. discloses an access system that is a flexible hollow guidewire support device or "flexible guide tube" (98) into which the insertion tube (14) is inserted, thus providing the necessary flexibility and maneuverability to advance through tortuous vasculature. (column 3, lines 14-20, column 13, lines 20-25, Fig. 15).

Application/Control Number: 10/559,759

Art Unit: 3731

 Regarding claim 10, Noriega et al. discloses a wire (22) made of a flexible material, i.e. nitinol or stainless steel having a diameter between 0.010 inches -.005 inches (.254mm- 0.127mm) which is approximately 0.2mm (column 9, lines 27-32, lines 55-57).

## Response to Arguments

Applicant's arguments with respect to claims 1 and 4-10 have been considered but are moot in view of the new ground(s) of rejection.

### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stevens (US Patent No. 5,116,350) and Stalker et al. (US Patent No. 5,908,395) are related to catheter systems for opening occluded blood vessels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4om.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/559,759 Page 5

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/ 7/11/2008 Examiner, Art Unit 3731

/Todd E Manahan/ Supervisory Patent Examiner, Art Unit 3731